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Re-evaluation Note REV2015-11

Special Review of Atrazine: Proposed Decision for Consultation

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) has initiated a special review of pest control products containing atrazine based on the decision taken by the European Commission in 2004. The initiation of the special review under the *Pest Control Products Act* was announced in December 2013 (Canada, 2013).

Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspect of concern that prompted the special review of pest control products containing atrazine. The aspect of concern is relevant to the environment and was related to the exceedance of atrazine and its chlorinated transformation products above the European Union regulated threshold of 0.1 µg/L in groundwater (i.e. related to the potential leaching of atrazine and its chlorinated transformation products into groundwater).

2.0 Uses of Atrazine in Canada

Atrazine is a broad-spectrum triazine herbicide. It is currently registered for use in corn (maximum rate: 1.5 kg a.i./year; applied 1-2 times per year) and in sorghum (Eastern Canada only; maximum rate: 1.0 kg a.i./ha applied once per year). It is applied using ground equipment. In Canada, atrazine underwent re-evaluation with completion of the human health risk assessment in 2004 (Canada, 2003; Canada, 2004) and the environmental risk assessment in 2007 (Canada, 2007a; Canada, 2007b). Appendix I lists all atrazine products that are currently registered under the authority of the *Pest Control Products Act*. The technical active ingredient, manufacturing concentrates and all end-use products containing atrazine are considered in this review. The proposed special review decision is applicable for all registered pest control products containing atrazine.

3.0 Aspect of the Pest Control Product that Prompted the Special Review

The use of atrazine in European Union Member States was banned in 2004 due to environmental concerns (European Commission, 2003; European Commission, 2004). The European Commission concluded that "*the information available is insufficient to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC. In particular the available monitoring data were insufficient to demonstrate that in large areas concentrations of the active substance and its breakdown products will not exceed 0.1 µg/l in groundwater. Moreover it cannot be assured that continued use in other areas will permit a satisfactory recovery of groundwater quality where concentrations already exceed 0.1 µg/l in groundwater*". The Rotterdam Convention Prior Informed Consent (PIC) Circular XXI (Rotterdam Convention, 2005) also provided similar information and indicated that the reasons for the European Union regulatory action were relevant to the environment and that the final regulatory action was not based on a risk or hazard evaluation.

Based on the review of the European Commission decision, the aspect of concern that prompted the special review of atrazine is related to the potential leaching of atrazine and its chlorinated transformation products (desethylatrazine (DEA) and desisopropylatrazine (DIA)) into groundwater.

4.0 PMRA Evaluation of the Aspect of the Pest Control Product that Prompted the Special Review

Following the initiation of the special review of atrazine, the PMRA requested information related to the aspect of concern from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the *Pest Control Products Act*. The information received that was relevant to the aspect of concern was considered in the special review.

In order to evaluate the potential for leaching of atrazine and its chlorinated transformation products (DEA and DIA) into groundwater, the PMRA has considered currently available relevant information (for example, environmental fate information from laboratory and field studies, available Canadian and American groundwater monitoring data, groundwater modelling, and information from the Canadian incident reporting database related to the aspect of concern).

Atrazine is soluble in water (33 mg/L at 20°C) and is expected to volatilize from moist soil or water as based on the Henry's law constant (2.61×10^{-4} Pa.m^3/mole). Atrazine has a low potential for bioaccumulation based on the *n*-octanol-water partition coefficient ($\log K_{ow} = 2.7$) (Canada, 2007a).

Hydrolysis is not a primary route of transformation of atrazine (stable in aqueous solution at pH 5, pH 7 and pH 9). Phototransformation on soil and in water are also not primary routes of transformation of atrazine (Canada, 2007a).

Several laboratory aerobic soil biotransformation studies were available and DT_{50} values varied (18–480 days). However, the majority of relevant studies indicated that DT_{50} values are between 40 and 115 days with a mean of 61 days. Based on this range of values, atrazine is moderately persistent in soil under aerobic conditions. In anaerobic soil, atrazine is also moderately persistent (DT_{50} = 77–159 days). In aerobic aquatic systems, atrazine is moderately persistent to persistent (DT_{50} = 80 to >400 days). Atrazine is persistent in anaerobic aquatic systems (DT_{50} = 330–608 days); thus, anaerobic aquatic biotransformation is not a primary route of transformation (Canada, 2007a). Based on the highest DT_{50} value in soil (480 days) and water (>400 days), atrazine meets the persistence criteria (≥182 days) under the Toxic Substances Management Policy (TSMP). However, it was determined that atrazine does not meet all of the TSMP Track 1 criteria (Canada, 2007a).

In addition to the laboratory transformation studies, the PMRA has considered field studies to assess the dissipation of atrazine. The dissipation of atrazine under Ontario field conditions indicated that atrazine is moderately persistent (half-life = 56–125 days). Under conditions representative of the temperate prairie ecozone in Canada, atrazine is reported to dissipate much

more slowly. Transformation products were first detected in soil at 450 days after the application of atrazine (Canada, 2007a).

Atrazine has medium to very high mobility in soil (adsorption K_{oc} = 39–155). The major chlorinated transformation products of atrazine (DEA, DIA and diaminochlorotriazine (DACT)), are highly mobile to very highly mobile in soil. Under field conditions, the majority of the applied material dissipates from the root zone, but traces of atrazine residues can leach into soil depths greater than one metre at approximately one year after application (Canada, 2007a). Therefore the PMRA has concluded that atrazine and its chlorinated transformation products have the potential to leach into groundwater.

Residues of atrazine in potential groundwater drinking water sources were estimated using modelling (Leaching Estimation and Chemistry Model (LEACHM)). At the screening-level (Level 1) the highest estimated environmental concentration (EEC) in groundwater was 164 µg/L of atrazine based on the use in corn in Quebec at a rate of 1.5 kg a.i./ha (Canada, 2003). In addition to modelling, groundwater monitoring data from both Canada and the United States were used to assess the potential leaching of atrazine and its transformation products to groundwater.

As part of the assessment, a search for groundwater monitoring data for atrazine in Canada and the United States was undertaken by the PMRA. The monitoring data (2005 to 2014) show that atrazine was detected in 2,823 out of a total of 14,455 groundwater samples (20%) from Canada and the United States. Considering only Canadian data, atrazine was detected in 11% of groundwater samples (119 out of 1067), with a maximum concentration of 2.32 µg/L. The maximum concentration of atrazine detected was 18.8 µg/L, in a spring water sample from the United States. Based on the Canadian reports currently available to the PMRA, the overall maximum detection of DEA in groundwater between the years 2005 and 2014 is 0.22 µg/L. The transformation products DIA and DACT were not detected during the same time period. Considering data from the United States over the same time period, the overall maximum concentrations of DEA, DIA and DACT in groundwater are 2.6 µg/L, 2.2 µg/L, and 2.9 µg/L, respectively. The differences in the numbers between the two countries may reflect a higher use of atrazine in the United States.

In addition, the technical registrant submitted a targeted drinking water monitoring study in 2006, from atrazine use areas (Ontario and Quebec) to monitor levels of atrazine and its chlorinated transformation products in Canadian raw and finished (untreated and treated) drinking water. The total chlorotriazine levels detected in this drinking water monitoring study did not exceed the Canadian drinking water guideline for atrazine (5 µg/L) and the chronic drinking water level of concern (41.9 µg/L)(Canada, 2007a; Canada, 2007b).

No concerns related to the aspect of concern (potential leaching of atrazine and its chlorinated transformation products into groundwater) were identified in the information received through the Canadian incident report database.

5.0 Drinking Water Risk Assessment

In addition to assessing the potential leaching of atrazine and its chlorinated transformation products into groundwater, the PMRA has conducted a scientifically based drinking water risk assessment to determine whether exposure to atrazine and its chlorinated transformation products through Canadian groundwater presents a potential risk of concern to Canadians.

Atrazine's chlorinated transformation products are considered to be equivalent in toxicity to atrazine, thus atrazine and its chlorinated transformation products were assessed together for the drinking water risk assessment. For acute dietary exposure, an acute reference dose (ARfD) of 0.04 mg/kg bw has been established by the PMRA for females aged 13+ years, based on a no observable adverse effect level (NOAEL) of 12.5 mg/kg bw/day derived from a 4-day rat study, and an uncertainty/safety factor of 300. For chronic dietary exposure, an acceptable daily intake (ADI) of 0.006 mg/kg bw/day has been established by the PMRA for all populations, based on a NOAEL of 1.8 mg/kg bw/day derived from a 6-month study in female rats, and an uncertainty/safety factor of 300 to provide an extra level of protection for the potential neuroendocrine modulating effects of atrazine (Canada, 2003; Canada, 2004).

For assessing risks from potential residues in drinking water, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data. The atrazine database contains the full complement of required studies including developmental studies in rats and rabbits, and a reproductive study in rats. There was no evidence of increased quantitative or qualitative sensitivity to rat or rabbit offspring following in utero and/or postnatal exposure to atrazine. Reference doses for atrazine were based on NOAELs for the most relevant endpoints, namely attenuation of the LH surge, estrous cycle alterations and developmental effects. These reference doses incorporate uncertainty factors to account for extrapolation between rats and humans and for variability within human populations, as well as an additional safety factor to provide an extra level of protection for the potential neuroendocrine modulating effects of atrazine. Therefore, in this context, the *Pest Control Product Act* factor could be reduced from 10-fold to 1-fold.

Drinking water exposure has been addressed by calculating, for each population subgroup, drinking water levels of comparison (DWLOCs) for acute and chronic exposure to atrazine and its chlorinated transformation products. The acute and chronic DWLOCs for the most sensitive population subgroup were 1300.5 and 41.9 µg/L, respectively (Canada, 2003). The maximum concentrations of atrazine and its chlorinated transformation products detected in groundwater based on available monitoring data (see Section 4.0) did not exceed either the acute or chronic DWLOCs for the most sensitive subpopulations. Therefore, residues of atrazine and its chlorinated transformation products in drinking water are not considered to be of concern to human health.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation). There are no domestic class end-use products containing atrazine currently registered for use in Canada, and atrazine commercial class end-use products are not registered for use in residential areas. On this basis, aggregate exposure is limited to food and drinking water only. As dietary exposure resulting from food intake comprises less than 1% for both acute and chronic exposure (Canada, 2003), and EECs of atrazine and its chlorinated transformation products detected in groundwater did not exceed the acute or chronic DWLOCs for the most sensitive subpopulations, aggregate exposure to food and drinking water is not of concern.

Atrazine, simazine and their common transformation products (DEA, DIA, DACT) share a common toxicity endpoint (neuroendocrine and neuroendocrine related developmental and reproductive effects) and a known mechanism of toxicity for this endpoint, namely that they can cause a disruption of the hypothalamic-pituitary-gonadal axis in rats by alteration of levels of luteinizing hormone (United States, 2006). The PMRA considered triazine cumulative effects (Canada, 2009) based on the 2006 assessment from the USEPA (United States, 2006). Exposure was estimated based on data from three American regions where exposure to triazine residues were likely to co-occur and which were representative of high-end exposure scenarios. Acceptable MOEs were reported for infants (younger than 1 year old), children (1–2 years old), females (13–49 years old) and males (20–49 years old), which represented the most vulnerable and sensitive groups relative to the endpoint of concern (NOAEL of 1.8 mg/kg/day). Therefore, the USEPA concluded that cumulative exposure to triazine residues through drinking water exposure was not of concern to human health. The USEPA's assessment is considered to be relevant to the Canadian situation, because Canadian maximum application rates are encompassed by those assumed in the USEPA's assessment. Currently, an updated cumulative assessment is ongoing as part of the USEPA Registration Reviews for atrazine, simazine and propazine (United States, 2013).

The European Union has adopted a level of 0.1 µg/L as the maximum acceptable concentration in groundwater for individual pesticides in 1998 (Annex I of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998). The 0.1 µg/L threshold is a legislated, rather than risk-based, value that applies to all pesticides regardless of their toxicity to humans. The PMRA follows a risk-based scientific approach in determining the risk to human health from pesticides in drinking water. This approach takes into consideration both the estimated level in drinking water sources and the toxicity of the pesticide. Based on the drinking water risk assessment of atrazine and its chlorinated transformation products, the PMRA concludes that there are no acute or chronic risks of concern from groundwater under the current conditions of use. However, to minimize the potential leaching of atrazine and its chlorinated transformation products, the labels of all registered end use products containing atrazine currently include environmental hazard statements to reduce the potential for leaching of atrazine residues into groundwater.

6.0 Proposed Special Review Decision for Atrazine

Evaluation of available relevant scientific information related to the aspect of concern, indicates that atrazine and its chlorinated transformation products do not pose unacceptable risks to human health and the environment, with respect to drinking water, taking into account the current conditions of use. On this basis, the PMRA, under the authority of the *Pest Control Products Act*, is proposing to confirm the current registration of pest control products containing atrazine for sale and use in Canada. This proposal affects all registered products containing atrazine in Canada.

This proposed special review decision is a consultation document.[1] The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

7.0 Next Steps

Before making a special review decision on atrazine, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on atrazine. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I Registered Products Containing Atrazine as of 25 November 2015

Registration Number	Marketing Class	Registrant	Product Name
18438	Technical	Syngenta Canada Inc.	Atrazine Technical
30373	Manufacturing Concentrate	Syngenta Canada Inc.	Atrazine Base Mix Manufacturing Concentrate
30726	Manufacturing Concentrate	BASF Canada Inc.	Marksman Bulk Herbicide
16641	Commercial	BASF Canada Inc.	Laddok Herbicide
18450	Commercial	Syngenta Canada Inc.	Aatrex Liquid 480 Herbicide
19349	Commercial	BASF Canada Inc.	Marksman Herbicide
25730	Commercial	Syngenta Canada Inc.	Primextra II Magnum Herbicide
26277	Commercial	Bayer CropScience Inc.	Converge 480 Herbicide
29164	Commercial	Syngenta Canada Inc.	Propero Herbicide
29358	Commercial	Syngenta Canada Inc.	Primextra II Magnum Agricultural Herbicide
30519	Commercial	BASF Canada Inc.	Frontier Max Plus
30864	Commercial	Syngenta Canada Inc.	Lumax EZ Herbicide
31846	Commercial	Syngenta Canada Inc.	Acuron Herbicide

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